UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS NOTICE

51-02

11/26/2002

THIRD-PARTY EQUIPMENT AND UTENSIL INSPECTION AND CERTIFICATION PROGRAMS FOR THE MEAT AND POULTRY PROCESSING INDUSTRY

I. PURPOSE

This Notice replaces FSIS Notice 25-02, dated 7/9/2002. This updated Notice provides additional information that Food Safety and Inspection Service (FSIS) inspection program personnel may find helpful in their day-to-day assessment of equipment used in Federally-inspected establishments. In addition, in the previous Notice, dated 7/9/2002, FSIS referred to only one organization that provides third-party review and acceptance of equipment and utensils. In this new Notice, FSIS is providing information on all known entities that review and accept equipment.

II. BACKGROUND

- A. FSIS proposed in the May 2, 1996, <u>Federal Register</u> (61 FR 19578) to amend its Federal meat and poultry products inspection regulations to eliminate requirements for FSIS prior approval of equipment and utensils proposed for use in preparing edible product or product ingredients in official establishments (9 CFR 308.5, 381.53).
- B. The final rule, "Elimination of Prior Approval Requirements for Establishment Drawings and Specifications, Equipment, and Certain Partial Quality Control Programs, [Docket No. 95-032F], was published in the <u>Federal Register</u> on August 25, 1997. Effective September 24, 1997, the Agency amended its regulations by removing the requirements for prior approval by FSIS of establishment drawings, specifications, and equipment used in official establishments.
- C. This final rule affords industry the flexibility to design facilities and equipment in the manner they deem best to maintain a sanitary environment for food production. Under this final rule, establishments are no longer required to use only FSIS-approved utensils and models of equipment, and FSIS no longer evaluates

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equipment or utensils for acceptance. However, FSIS inspection program personnel will continue to verify that establishments maintain equipment and utensils in a manner that meets the sanitation performance standards in 9 CFR 416.3. Adequate sanitary design of equipment is ensured through establishment implementation of Sanitation Standard Operating Procedures (Sanitation SOPs) and Hazard Analysis and Critical Control Point (HACCP) systems. Equipment and utensils must continue to meet the general standard that they are of such material and construction that will facilitate their thorough cleaning, ensure cleanliness in the preparation and handling of all edible products, and avoid adulteration and misbranding of such products. In addition to these requirements, equipment and utensils are not to interfere or impede in any way with the inspection procedures. FSIS also has authority to prevent the use of equipment or facilities that pose a threat to public health.

- D. Under this Final Rule, FSIS agrees that third-party certification services may be advantageous to an establishment in developing and implementing Sanitation SOPs and HACCP plans, but states that such certification services are not mandatory, rather strictly voluntary. Although third-party certification is voluntary, it will ensure that equipment and utensils meet minimum requirements for cleanability, suitability of materials used in construction, durability, and inspectability.
- E. FSIS Directive 11,000.1, dated 1/25/00, was issued to provide instructions on how to verify sanitation in an establishment and to ensure that sanitation is consistent with the final rule on Sanitation Requirements for Official Meat and Poultry Establishments, which was effective January 25, 2000. The rule consolidated the sanitation regulations into a single part applicable to both official meat and poultry establishments and converted many of the highly prescriptive sanitation requirements to performance standards. Section 416.1 of the Sanitation Performance Standards (06D01) states that "Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated."
- F. Under this final rule, establishments that met the relevant sanitation requirements before the promulgation of the rule did not have to do anything differently to continue to remain in compliance. The rule also did not affect an establishment's obligation to comply with applicable Food and Drug Administration, Environmental Protection Agency, and Occupational Safety and Health Administration regulations.
- G. Though establishments can use different and varying means to meet these performance standards, the required results must always be the same. Establishments must prevent insanitary conditions that could lead to adulterated product.

III. Why is FSIS providing this information?

FSIS is providing this information to increase inspectors' awareness of what they might see upon review of equipment in establishments, or upon review of establishment records.

IV. Who can provide this third-party certification?

The three groups known to FSIS that provide third-party certification services are Underwriters Laboratories Inc. (UL), Melville, New York; NSF, Ann Arbor, Michigan; and the Agricultural Marketing Service (AMS), Washington, D.C.

Questions pertaining to third-party certification services can be directed to the groups as listed below:

Underwriters Laboratories Inc. (UL) Food Safety Program 1285 Walt Whitman Road Melville, NY 11747-3081

Contact Person: Donna Bonanno

Telephone No.: 631-271-6200, Ext. 22381 e-mail: Donna.Bonanno-Galluccio@us.ul.com

website: http://www.ul.com/foodsafety

NSF 789 North Dixboro Road Ann Arbor, MI 48105

Telephone No.: 1/800/NSF-MARK or 734-913-5729

e-mail: http://www.nsf.org

Agricultural Marketing Service (AMS) 14th & Independence Avenue, S.W. Dairy Grading Branch Stop 0291 Washington, DC 20250-0291 Contact Person: Evan Stachowicz

Telephone No.: 202-720-8307 e-mail: evan.stachowicz@usda.gov

V. Are establishments required to use equipment that meets standards for third-party certification?

No. This is a voluntary program.

VI. Do inspection program personnel have responsibilities related to the third-party certification?

No. The purpose of this notice is to inform inspection program personnel about third party certification that an establishment may have obtained.

VII. Does an establishment's participation in third-party certification ensure compliance with FSIS regulations?

No. Inspection program personnel will continue to verify that establishments maintain equipment and utensils in a manner that meets the sanitation performance standards in 9 CFR 416.3.

VIII. How do inspection program personnel ensure that there is compliance with the Sanitation Performance Standards?

- A. As scheduled by PBIS, the inspection program personnel will use Inspection System Procedure (ISP) code 06D01 to verify that establishments are operating in accordance with the sanitation performance standards. They may directly observe conditions in the establishment or review records to verify that the establishment is complying with the sanitation performance standards. When ISP code 06D01 is scheduled by PBIS, the inspection program personnel should perform verification activities for one or more of the sanitation performance standards regulations to verify establishment compliance. The inspection program personnel should use their professional judgment as to which verification activities need to be performed. As a general rule, they should randomly determine which sanitation performance standard they should verify and try to vary the verification of performance standards. When they suspect any possible noncompliance with any of the sanitary performance standards, they are to perform an unscheduled 06D01.
- B. If the inspection program personnel identify a potential problem with the cleanability, durability, suitability, or inspectability of the equipment, they will ask for documentation, including any third-party certification, and assess the information. Substantive concerns will be directed by the inspection program personnel to the Technical Service Center (TSC). The TSC will work with the Office of Policy and Program Development (OPPD) in situations in which equipment has been accepted as being cleanable, durable, suitable, and inspectable, but if FSIS disagrees based upon inspection program personnel input, then OPPD will follow-up with the TSC on resolving this situation.

IX. What are the regulatory performance standards for equipment and utensils (FSIS Directive 11,000.1)?

Section 416.3 states:

- (a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.
- (b) Equipment or utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from safety inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

X. What do the performance standards mean?

Establishments have the flexibility to choose whatever method they want to clean equipment and utensils; however, the method must result in equipment and utensils that are maintained in a sanitary condition so as not to adulterate product.

XI. How do the inspection program personnel verify compliance?

- A. Check to ensure that equipment does not hinder efficient inspection.
- B. Check equipment and utensils to ensure that they are sanitary and able to be cleaned.
- C. Check to ensure that receptacles used for storing inedible product are properly and conspicuously marked.

Refer questions to the Technical Service Center.

Philip S. Derfler /s/

Deputy Administrator
Office of Policy and Program Development